Medical Necessity Guideline

Medical Necessity Guideline Title: Modified T-Cell Therapy		
MNG #: 01	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☒Yes ☐ No**	**Approval Date:** 1/10/2019;	**Effective Date:** 4/01/2019;
Last Revised Date: 1/25/2019; 03/25/2020; 3/26/2021	**Next Annual Review Date:** 1/10/2020; 3/25/2021; 3/26/2022	**Retire Date:**

OVERVIEW:

Cancer is a collection of related diseases of dividing cells that can start almost anywhere in or on the body, evade the immune system, and invade nearby tissues. Categories of cancer are typically organized by the location in the body and specific type of cell. These categories may include carcinoma, sarcoma, leukemia, lymphoma, multiple myeloma, melanoma, and brain and spinal cord tumors. There are also changes to these cells that are not considered cancer. These changes include hyperplasia—when a cell divides faster than normal—and dysplasia—a buildup of extra cells with abnormal shape and disorganization.

A person's immune system contains cells to help fight substances that are foreign to the body, including cancer. These cells are called white blood cells, most of which are lymphocytes. The two main types of lymphocytes are B lymphocytes (B-cells) and T lymphocytes (T-cells). B-cells generate and release antibodies to fight infection, especially bacterial infections, while T-cells employ a number of other mechanisms to fight abnormal cells such as cancer. One type of therapy that leverages the immune system—immunotherapy—is Chimeric Antigen Receptor (CAR) T-cell therapy.

CAR T-cells have been genetically altered in order to improve the ability of the T-cells to fight cancer. The genetic modification creating a CAR can enhance the ability of the T-cell to recognize and attach to a specific protein, called an antigen, on the surface of a cancer cell. Current FDA-approved CAR-T cell therapies include: Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autleucel, KTE-X19), and Breyanzi (Lisocabtagene maraleucel).

DECISION GUIDELINES:

Clinical Eligibility:

Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) -i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

KYMRIAH™ (Tisagenlecleucel)

Commonwealth Care Alliance may authorize coverage of KYMRIAH™ (tisagenlecleucel) when the following criteria are met:

<u>CD-19 positive B-cell precursor acute lymphoblastic leukemia</u>

1. The Member is age 25 years of age or younger.
2. The Member has been diagnosed with CD-19 positive B-cell precursor acute lymphoblastic leukemia.

3. The disease is refractory to treatment or is in its second or greater relapse.
4. The Member has had no prior treatment with tisagenlecleucel or other CAR T-cell therapy.
5. The Member does not have active, uncontrolled CNS disease.
6. The Member does not have:
    a. HIV, active hepatitis B or C infection
    b. Active uncontrolled infection
    c. Autoimmune disease requiring vv v vvimmunosuppression
7. For members with a history of an allogeneic Hematopoietic Stem Cell Transplant (HSCT), there is no evidence of active Graft versus Host Disease (GVHD) requiring treatment.
8. The treating facility is certified under the KYMRIAH™ Risk Evaluation and MitigationStrategy (REMS) System program. More information is available at https://www.us.kymriah.com/treatment-center-locator/

CD-19 positive large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma

1. The Member is age 18 years of age or older.
2. The Member has been diagnosed with CD-19 positive large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma.
3. The Member has received two or more lines of systemic therapy.
4. The Member has had no prior treatment with tisagenlecleucel or other CAR T-cell therapy.
5. The member does not have primary CNS lymphoma.
6. The Member does not have:
    a. HIV, active hepatitis B or C infection
    b. Active uncontrolled infection
    c. Autoimmune disease requiring immunosuppression.
7. For members with a history of an allogeneic Hematopoietic Stem Cell Transplant (HSCT), there is no evidence of active Graft vs Host Disease (GVHD) requiring treatment.
8. The treating facility is certified under the KYMRIAH™ Risk Evaluation and MitigationStrategy (REMS) System program. More information is available at https://www.us.kymriah.com/treatment-center-locator/

YESCARTA™ (axicabtagene ciloleucel)

Commonwealth Care Alliance may authorize coverage of YESCARTA™ (axicabtagene ciloleucel) when the following criteria are met:

1. The Member is age 18 years of age or older.
2. The Member has been diagnosed with CD19-positive large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma.
3. The member has received two or more lines of systemic therapy.
4. The Member has had no prior treatment with axicabtagene ciloleucel or other CAR T-cell therapy.
5. The member does not have primary CNS lymphoma.
6. The Member does not have:
    a. HIV, active hepatitis B or C infection
    b. Active uncontrolled infection
    c. Autoimmune disease requiring immunosuppression.
7. For members with a history of an allogeneic Hematopoietic Stem Cell Transplant (HSCT), there is no evidence of active Graft vs

Host Disease (GVHD) requiring treatment.

8. The treating facility is certified under the YESCARTA™ Risk Evaluation and MitigationStrategy (REMS) System program. More information is available at https://www.yescarta.com/treatment-centers.

TECARTUS™ (brexucabtagene autoleucel)

Commonwealth Care Alliance may authorize coverage of TECARTUS™ (brexucabtagene autoleucel) when the following criteria are met:

1. The Member is age 18 years of age or older.
2. The Member has been diagnosed with CD19-positive Mantle cell lymphoma that has either relapsed or is refractory to first-line systemic therapy.
3. The Member has had no prior treatment with brexucabtagene autoleucel.
4. The member does not have primary CNS lymphoma.
5. The Member does not have:
    a. HIV, active hepatitis B or C infection
    b. Active uncontrolled infection
    c. Autoimmune disease requiring immunosuppression.
6. The treating facility is certified under the YESCARTA™ Risk Evaluation and MitigationStrategy (REMS) System program. More information is available at https://www.tecartus.com/find-a-treatment-center

BREYANZI™ (Lisocabtagene maraleucel)

Commonwealth Care Alliance may authorize coverage of BREYANZI™ (Lisocabtagene maraleucel) when the following criteria are met:

1. The Member is age 18 years of age or older.
2. The Member has been diagnosed with CD19-positive large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified and DLBCL arising from indolent lymphoma, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.
3. The member has received two or more lines of systemic therapy including previous immunochemotherapy containing ant-CD20 and anthracycline with subsequent relapse.
4. The Member has had no prior treatment with Lisocabtagene maraleucel.
5. The Member does not have:
    a. HIV, active hepatitis B or C infection
    b. Active uncontrolled infection
    c. Autoimmune disease requiring immunosuppression.
6. The treating facility is certified under the YESCARTA™ Risk Evaluation and MitigationStrategy (REMS) System program. More information is available at https://www.yescarta.com/treatment-centers.

LIMITATIONS/EXCLUSIONS:

1. Effective for services performed on or after August 7, 2019, the use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered.
2. Autologous treatment for cancer with T-cells expressing at least one CAR is non-covered when the requirements noted above are not met.
3. CAR-T cell therapy is contraindicated in pregnancy.
4. Members with untreated underlying primary immunodeficiency syndromes will not be approved for CAR-T cell therapy.
5. Members with active and/or metastatic malignancy that is unlikely to respond to treatment will not be approve for CAR-T therapy.

6. Members who have had prior treatment with any form of CAR-T cell therapy, including therapies in clinical trial settings, will not be approved for additional CAR-T therapy.
7. CAR-T therapy will not be covered if the Member demonstrates clinical decompensation from time of authorization to time of infusion and no longer meets clinical coverage criteria.

KEY CARE PLANNING CONSIDERATIONS:

Any indications for CAR-T cell therapy other than those outlined above are considered investigational and will not be covered.

AUTHORIZATION:

N/A

REGULATORY NOTES:

N/A

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. MassHealth Drug List Table 75: Chimeric Antigen Receptor (CAR)-T Immunotherapies, Section III: Evaluation Criteria for Approval. https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=353. Accessed 3/26/2021.

2. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Manual section number 110.24 version 1, effective date 8/7/2019, implementation date 2/16/2021. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&KeyWord=chimeric&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA. Accessed 3/26/2021.

3. Axicabtagene ciloleucel. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. http://www.micromedexsolutions.com. Accessed 3/26/2021.

4. Tisagenlecleucel. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. http://www.micromedexsolutions.com. Accessed 3/26/2021.

5. Brexucabtagene autleucel. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. http://www.micromedexsolutions.com. Accessed 3/26/2021.

6. Lisocabtagene maraleucel. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. http://www.micromedexsolutions.com. Accessed 3/26/2021.

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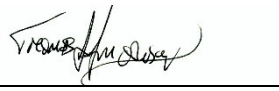
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Thomas A. Amoroso, MD	Medical Director, Utilization Management
CCA Senior Clinical Lead [Print]	**Title [Print]**
	1/4/2019
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Lori Tishler, MD	Senior Vice President, Medical Affairs
CCA CMO or Designee [Print]	**Title [Print]**
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